

List of Conclusions and Resolutions

agreed at the 37th Meeting of the EA Advisory Board
held on 12 October 2016

Agenda Item 2 - Approval of agenda; Approval of Minutes of 36th Meeting of the EA Advisory Board; Action list (actions not covered elsewhere)

▪ Action List

The Board:

- agrees that the discussions on the need for consistency and harmonisation among NABs, which should have been supported by a paper drafted by the CAB College at this meeting, should be postponed at a later meeting, acknowledging the continued importance of these issues;
- thanks Pierre de Ruvo who proposed to make the issue progress and improve by feeding the next outcome of a current survey led by ETICS into the future discussions of the Board.
Action P. de Ruvo

Agenda Item 3 - EAAB matters

Agenda Item 3.1 - Reports from the EAAB HHC and MAC observers

The Board:

- thanks Andrew Evans and Maureen Maria Logghe for their comprehensive written reports on, respectively, the last EA HHC and MAC meetings held on 20-21 September and 5-6 October 2016, and takes note of the various issues addressed in them;
- takes note in particular of the CAB and Industry Colleges' concern about the lack of clarity of the process for the evaluation of conformity assessment schemes by EA-member NABs, especially when other ABs disagree on the "home AB" recommendation, and welcomes EA's reassurance that the revised and currently balloted EA-1/22: *EA Procedure and Criteria for the Evaluation of Conformity Assessment Schemes by EA Accreditation Body Members* should clarify a number of points, notably regarding schemes owned by the European Commission, and EA's will to include further feedback on new experiences into a later revision of the document, if needed;
- appreciates that EA is open to give stakeholders the possibility to observe peer evaluations as a trust-building process, provided that their area of activity is covered and they are able to demonstrate a justified interest in observing a specific peer evaluation, and that any participation of third parties needs the consent of the parties involved;
- takes note that the EA MAC is discussing how to adopt a more effective approach with respect to reactions on non-conformities with NABs, in order to achieve MAC decisions more rapidly and to ensure proper enforcement of these decisions, while asking EA to make sure that the MAC's decision-making process is such that it does not undermine the peer-evaluation system with respect to a timely decision and reinforce its credibility;

- agrees that, in their specific roles, EAAB observers at the HHC and MAC meetings carry out a function on behalf of the entire Board to ensure that it can effectively perform the tasks of the stakeholder structure as referred to in Regulation (EC) 765/2008 and in the Framework Partnership Agreement between the EC and EA, and that therefore the meeting-related costs (fees for meeting rooms, etc.) incurred by the EAAB observers should be borne by EA.

Action EA

Agenda Item 3.2 - EAAB Work Programme

The Board agrees to close the topic entitled “*Adaptability of the rules and conditions relating to EA membership and EA MLA signatory status for smaller ABs*” mentioned on Page 1, on the understanding that EA makes sure that the peer-evaluation system continues to pay due attention to ABs in terms of technical competencies (concerning both the technical competencies in the AB itself to decide on accreditations and the technical competencies of experts who perform the assessments).

Action EAAB Secretariat to classify the topic as closed on the WP

Agenda Item 3.3 - Stakeholders’ involvement in EA committees, working and task force groups, etc.

The Board:

- thanks EA for reminding stakeholders that it is up to themselves to actively contribute to committees’ discussions, especially the technical ones, and for urging them to do so;
- confirms its interest and incentive role in stakeholders’ involvement in EA committees and WGs/TFGs, supporting each college and stakeholder organisation to join relevant EA structures.

Agenda Item 4 - EA matters

Agenda Item 4.1 - Consistency and harmonisation among ABs

This item was changed to 4.1 - Report on results of AfN project & next steps as revision of EA-2/17

The Board:

- thanks EA for the comprehensive work achieved with the AfN (Accreditation for Notification) project, especially for the resulting Annex that lists the *Directory of Preferred Harmonized Standards per EC Directive/Regulation and module*;
- notes that the Industry College questions the justification for the differences in the preferred standards for the quality assurance modules D and E (and its variants) as opposed to modules H and H1, as in the view of the Industry College, all these quality assurance modules have been conceived to ensure product conformity in the same way, using quality management techniques (albeit to a varying extent). In the view of the Industry College, it should be possible to use either 17065 or 17021 as alternative standards for the accreditation of bodies in view of their notification under the quality assurance modules (D, D1, E, E1, H and H1).

Agenda Item 4.2 - Project on EA Strategy 2025 (follow-up)

The Board:

- appreciates the work as progressed so far by EA;
- strongly supports the strategic objectives defined in the project report, and is looking forward to their implementation.

Agenda Item 4.4 - New EA projects and work items

The Board endorses the proposed new work items for:

- revision of EA-0/07: *EA Procedure for application for EA membership and application form*;
- revision of EA-1/06: *EA Multilateral Agreement. Criteria for signing. Policy and procedures for development*;
- revision of EA-1/17: *EA Rules of Procedure*;
- revision of EA-1/17 S4: *Proxy Procedure*;
- review/revision of EA-2/14: *Procedure for Regional Calibration ILCs in Support of the EA MLA*;
- elaboration of informative document on *Joint EA - EDQM Communication regarding cooperation when carrying out joint audits/assessments in Official Medicines Control Laboratories*.

Agenda Item 4.5 - Revisions of ISO/IEC 17011 and ISO/IEC 17025

The Board takes note that:

- the CAB College does not support the revision of ISO/IEC 17065 in 2017 and the need for guidance on the current standard, and asks EA to support this at e.g. IAF/ILAC TCs and GAs, ISO-IAF-ILAC JSC, etc.;
- EA members are fully aware of the ongoing discussions on the possible postponement of the revision of the ISO-series standards in 2017, which has been considered at the last meetings of EA committees.

Agenda Item 5 - Items for information

Agenda Item 5.1 - Information to the EAAB

The Board:

- thanks EA for the oral reports provided under this item;
- about **Breast Cancer Services (BCS) project**, takes note of the Industry College's concerns regarding the coverage of the guidelines for use by BCS, and asks EA to ensure that any duplication of certification of medical devices that have already been certified under the Medical Devices Directive is avoided.

Agenda Item 5.2 - CETA - Implementation of the Bilateral Cooperation Agreement with Canada/SCC - Progress report

Agenda Item 5.3 - Report on complaints and appeals

Agenda Item 5.5 - Draft Agenda of the 38th EA GA on 23-24 November in Boras, Sweden

The Board thanks EA for the oral and written reports provided under these items.

Agenda Item 5.4 - IAF/ILAC Annual meetings on 26 Oct. - 4 Nov. 2016

The Board:

- thanks EA for its oral report;
- about **granting of accredited management system certificates in the accredited scope only**, further to IIOC's demonstrating this as a perfect illustration of inconsistency between EA ABs having already or not implemented the IAF decision, would appreciate a clear communication from EA and a clear guidance on implementation by EA members.
Action EA

Agenda Item 8 - Selection of dates and places of next meetings

The Board:

- confirms the next EAAB meeting on **Friday 28 April 2017 starting at 10 am** at the EFTA Secretariat, which was warmly thanked;
- agrees to meet on **Thursday 12 October 2017**.

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